No. 25 - 1093

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

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IN RE WALMART INC.,

*Petitioner.*

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On Petition for a Writ of Mandamus to
the United States Drug Enforcement Administration

# PETITION FOR A WRIT OF MANDAMUS

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## CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1, Petitioner provides the following statement:

Walmart Inc. does not have a parent corporation, nor is there any publicly held corporation that owns 10% or more of its stock.

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## INTRODUCTION

Amidst an unprecedented opioid crisis impacting millions of Americans, most pharmacists and pharmacy owners, including Walmart, are doing their best to comply with the Controlled Substances Act (CSA) while respecting their obligations to patients, federal and state regulators, law enforcement agencies, and others. But a lack of regulatory clarity from the U.S. Drug Enforcement Agency (DEA) and Department of Justice (DOJ)—including shifting and contradictory positions in those agencies' enforcement actions and informal guidance—has hindered that work. Indeed, because DEA has not implemented any formal rules governing pharmacists' opioid-prescription obligations under the CSA, pharmacists and pharmacies are between a rock and a hard place: threatened with liability both for going *too far* and for not going *far enough* in refusing to fill opioid prescriptions.

Walmart petitioned DEA in November 2020 to promulgate rules clarifying the obligations of prescribers, pharmacists, and pharmacies under the CSA. The Administrative Procedure Act (APA) requires DEA to respond to that petition without "unreasonabl[e] delay[]." 5 U.S.C. § 706(1); *see also id.* § 555(b). But more than four years later, DEA has said and done nothing in response. During those four years, the irreconcilable pressures on pharmacists and pharmacies have only grown worse. Walmart is left with no choice but to seek a writ of mandamus requiring DEA to act.

Relevant law reflects the differences in training and expertise between prescribers and pharmacists. Prescribers—who must be registered with DEA to prescribe controlled substances—attend medical school, examine patients, assess medical records, and then exercise case-specific medical judgment to issue prescriptions. Accordingly, prescribers are responsible "for the proper prescribing and dispensing of controlled substances," and may issue prescriptions only "for a legitimate medical purpose ... in the usual course of [the prescriber's] professional practice." 21 C.F.R. § 1306.04(a). Pharmacists, by contrast, do not possess medical degrees, do not conduct medical exams, cannot access medical files, and may not engage in the practice of medicine. They necessarily depend on prescribers when filling prescriptions and therefore have a "corresponding responsibility" not to "*knowingly* fill[]" a prescription "issued not in the usual course of professional treatment." *Id.* (emphasis added). That "knowingly" element is important because, as DEA itself has recognized, pharmacists are not equipped to second-guess a prescriber's medical judgment by "determin[ing] the legitimacy of a prescription." *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7,776, 7,777 (April 24, 1971).

Although the law reflects a clear division of responsibilities between physicians and pharmacists, reality is quite different. On the one hand, DOJ and DEA have demanded that pharmacists and pharmacy owners take certain steps that

the agencies believe will reduce problematic prescriptions. But when the pharmacists and pharmacy owners take those steps, they are faced with state medical licensing boards, medical associations, and individual litigants arguing that those steps are illegal. For example, in response to increased DOJ and DEA pressure to curb dispensing of opioid prescriptions, Walmart refused to fill certain questionable prescribers' controlled substance prescriptions. As a result, Walmart was met with state investigations and lawsuits alleging that Walmart was improperly interfering with medical practice and second-guessing doctors' medical judgment. At the same time, DOJ and DEA sued Walmart for not going far enough to block entire categories of prescriptions.

Walmart's Petition for notice-and-comment rulemaking—filed more than four years ago—sought to provide prescribers, pharmacists, and pharmacies with some measure of regulatory clarity. But the only response Walmart has received from the federal agency responsible for administering the Nation's drug laws is silence. DEA's protracted delay in responding to Walmart's Petition is unreasonable and violates the APA. It prejudices the pharmacies and pharmacists caught between irreconcilable demands and put to impossible choices. And it harms those patients who cannot access the prescription medications they need. Nor can DEA's foot-dragging be excused based on competing priorities. DEA itself has proclaimed the urgency of this issue—while refusing to provide regulatory clarity for pharmacists

and pharmacy owners. All the while, DOJ pours its considerable resources into nationwide litigation seeking to enforce duties that appear nowhere in the statute or regulations.

Walmart's request for relief from this Court is modest. Walmart does not seek an order requiring DEA to promulgate any particular rule, or even to promulgate a rule at all. Walmart seeks only an order requiring DEA to respond to the Petition: The agency must either initiate a rulemaking or expressly decline to do so.

## RELIEF SOUGHT

This Court should grant a writ of mandamus and order DEA to respond to Walmart's rulemaking Petition within 30 days.

## JURISDICTIONAL STATEMENT

Because Walmart's principal place of business is in Arkansas, this Court would have jurisdiction to review a DEA order resolving Walmart's Petition. *See* 21 U.S.C. § 877 ("[A]ny person aggrieved by a final decision of the Attorney General [under this subchapter] may obtain review of the decision in the United States Court of Appeals ... for the circuit in which his principal place of business is located upon petition filed with the court[.]"); *see also* 28 C.F.R. § 0.100(b) (delegating authority to DEA administrator). Thus, this Court has jurisdiction under 28 U.S.C. § 1651 to resolve Walmart's "claim[] of unreasonable delay in order to protect its future jurisdiction" over such final decision. *Telecomms. Rsch. & Action*

*Ctr. v. FCC ("TRAC")*, 750 F.2d 70, 76 (D.C. Cir. 1984). This Court has left open whether such a claim is "reviewed under [5 U.S.C.] § 706(1) or as a petition for a writ of mandamus." *Org. for Competitive Markets v. U.S. Dep't of Agric.*, 912 F.3d 455, 462 (8th Cir. 2018); *see also* 5 U.S.C. § 706(1) (the "reviewing court shall ... compel agency action ... unreasonably delayed"). Under either approach, this Court has jurisdiction.

## ISSUE PRESENTED

Whether DEA's four-year delay in issuing any response to Walmart's Petition is unreasonable.

## STATEMENT OF FACTS

### A. Walmart Pharmacies[1]

Although Walmart is not principally a pharmacy, it operates more than 5,000 in-store pharmacies nationwide. Walmart's pharmacies serve an array of local communities and offer customers one-stop shopping. Walmart's pharmacy operations disproportionately help those with limited financial resources. Each year, Walmart fills prescriptions for millions of customers on Medicare, Medicaid, and TRICARE—the insurance system for military personnel, veterans, and their families. Nearly half of the prescriptions Walmart fills are paid for by one of these programs.

[1] *See* Petition (Ex. 1) at 3.

Walmart's dispensing policies have always complied with the letter and spirit of the CSA. Above all, Walmart has consistently supported pharmacists in the discharge of their duties. Walmart has long encouraged pharmacists to exercise their professional judgment and to refuse to fill opioid prescriptions that they do not believe to be valid. In fact, Walmart pharmacists have refused to fill hundreds of thousands of opioid prescriptions. Walmart has also adopted innovative opioid-stewardship programs and partnered with law enforcement agencies, including DEA, to help root out corrupt doctors and put them behind bars.

### B. Pharmacies' Conflicting Obligations[2]

Despite those efforts, DOJ and DEA have placed Walmart and other pharmacists and pharmacies in an untenable position by seeking to hold them liable for violating unwritten expectations and non-binding guidance limiting the filling of opioid prescriptions. For example, DOJ sued Walmart in 2020 for massive civil penalties under several such theories. It attacked Walmart's supposed failure to document the steps the government contends pharmacists should take to scrutinize prescriptions written by DEA-registered doctors.[3] DOJ has claimed that certain prescriptions—even when written by registered physicians—are so facially unlawful

[2] *See id.* at 3-4.

[3] *See* Am. Compl. ¶¶ 8, 74, 90, 547, 556, *United States v. Walmart*, No. 1:20-cv-01744-CFC (D. Del. Oct. 7, 2022), ECF No. 75 ("Am. Del. Compl.").

that merely filling them subjects a pharmacist and pharmacy to liability under the CSA.[4] These theories disregard the CSA's fundamental scienter requirement.[5]

In response, Walmart has adopted a more aggressive approach to opioid dispensing—choosing, for instance, to block categorically the dispensing of controlled substance prescriptions written by certain registered prescribers and to restrict the dispensing of certain kinds of opioids. But as a direct result of those efforts, Walmart has faced questions, lawsuits, and investigations from doctors, patients, legislators, and state boards of medicine and pharmacy claiming that Walmart's responsive actions interfere with the doctor-patient relationship in violation of state (and even federal) law.[6] These conflicting demands leave pharmacists in legal limbo while threatening patients' health and welfare.

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[4] *See id.* ¶¶ 482, 508.

[5] Plaintiffs' lawyers have followed DOJ's and DEA's lead, suing Walmart for billions based on closely related theories of liability that cannot be reconciled with the CSA's scienter requirement. *See, e.g., In re Nat'l Prescription Opiate Litig.*, 589 F. Supp. 3d 790, 809 & n.82 (N.D. Ohio 2022) (upholding jury verdict based on pharmacies' alleged failure to "maintain effective controls against diversion" in violation of 21 C.F.R. § 1307.71(a) because they "filled thousands of prescriptions presenting red flags without evidence of resolving those red flags"), *appeal pending sub nom. Trumbull County v. Purdue Pharma.*, No. 22-3753 (6th Cir.). *But see In re Nat'l Prescription Opiate Lit.*, No. 2023-1155, 2024 WL 5049302 (Ohio Sup. Ct. Dec. 10, 2024) (holding pharmacies could not be held liable for opioid epidemic on public nuisance theory).

[6] *See* pp. 20-23, *infra*.

### C. Walmart's 2020 Petition For Rulemaking

On November 24, 2020, pursuant to 5 U.S.C. § 553(e), Walmart petitioned DEA to promulgate rules addressing (1) "[t]he obligations of a pharmacist relative to those of a prescribing physician," (2) "[t]he obligations of a prescriber or a pharmacist to identify, investigate, document, and otherwise act on 'red flags' or other indicia beyond the four corners of a facially valid prescription," (3) "[t]he extent to which violations of state medical or pharmacy licensing rules trigger federal CSA liability," and (4) "[t]he obligations of a pharmacy business or owner ... beyond the duties owed by an individual pharmacist employee," if any.[7]

Nine days later, Walmart received a one-sentence email from DEA acknowledging receipt of the Petition.[8] After six months had passed without a substantive response, Walmart submitted a letter explaining that the APA required DEA "to answer within a reasonable time" and requesting DEA's position by June 7, 2021.[9] To date, DEA has not responded or indicated when it will do so.

In the meantime, DOJ continues to pursue pharmacies for alleged violations associated with filling opioid prescriptions. Last month, the United States filed a multi-count complaint against CVS, alleging that for more than ten years CVS

[7] Ex. 1 at 18-21.

[8] DEA Email (Dec. 2, 2020) (Ex. 2).

[9] Walmart letter to Tom Prevoznik, DEA (May 24, 2021) (Ex. 3).

pharmacies dispensed opioid prescriptions despite alleged "red flags."[10] And just a few days ago, the United States filed a similar complaint against Walgreens.[11] Yet neither DOJ nor DEA has ever indicated why DEA has not acted on a petition for rulemaking that—more than four years ago—sought regulatory clarity on the "red flags" that pharmacists should look for when filling facially valid opioid prescriptions.

## STATEMENT OF REASONS THE WRIT SHOULD ISSUE

DEA's unexplained silence violates the APA, which empowers courts to "compel agency action … unreasonably delayed." 5 U.S.C. § 706(1). DEA's four-year period of inaction with respect to Walmart's Petition would be unreasonable under any circumstance; given the health and welfare interests at stake here, the agency's delay is indefensible. Nor can it be said that a response to the Petition would interfere with other agency activities of a higher priority, given that DOJ and DEA themselves have recognized the importance of clarifying obligations relevant to the opioid crisis.

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[10] *See* Consol. Compl. in Intervention, *United States ex rel. Estright v. CVS Pharmacy, Inc.*, No. 1:22-cv-222-WES-PAS (D.R.I. Dec. 13, 2024), ECF No. 52 ("CVS Compl.").

[11] *See* Compl. in Intervention, *United States v. Walgreens Co., et al.*, No. 1:18-cv-05452 (N.D. Ill. Jan. 16, 2025), ECF No. 58 ("Walgreens Compl.").

## I. DEA Has A Legal Duty To Resolve The Petition For Rulemaking Without Unreasonable Delay.

The APA requires DEA to "conclude a matter presented to it" "within a reasonable time," 5 U.S.C. § 555(b), and authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1). That is because "excessive delay saps the public confidence in an agency's ability to discharge its responsibilities and creates uncertainty for the parties, who must incorporate the potential effect of possible agency decision making into future plans." *Potomac Elec. Power Co. v. ICC*, 702 F.2d 1026, 1034 (D.C. Cir. 1983). The agency has a "nondiscretionary duty" to act with reasonable expedition, *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1099 (D.C. Cir. 2003), even when the petition asks for "discretionary action," as with a petition for rulemaking. *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004); *see, e.g., Families for Freedom v. Napolitano*, 628 F. Supp. 2d 535, 540 (S.D.N.Y. 2009) (holding agency's unreasonable delay responding to petition for rulemaking violated the APA). Regardless of the "answer [the agency] might ultimately give the petitioners," an agency's prolonged "failure to give ... *any* answer" is unreasonable. *Am. Rivers & Idaho Rivers United*, 372 F.3d at 419.

## II. DEA's Delay Is Unreasonable.

To evaluate whether the agency's delay is reasonable, federal courts apply a six-factor test established by the D.C. Circuit in *Telecommunications Research and*

*Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC*"). This Court has indicated on several occasions that *TRAC* controls in mandamus cases. *See Irshad v. Johnson*, 754 F.3d 604, 607 (8th Cir. 2014); *Org. for Competitive Markets*, 912 F.3d at 463 n.6. Indeed, "*TRAC* has been widely followed by federal courts" as the "seminal test for unreasonable delay." *Families for Freedom*, 628 F. Supp. 2d at 540 (internal quotation marks omitted); *see, e.g.*, *Vaz v. Neal*, 33 F.4th 1131, 1137 (9th Cir. 2022); *Kramer v. Wilkie*, 842 F. App'x 599, 603 (Fed. Cir. 2021); *Gonzalez v. Cuccinelli*, 985 F.3d 357, 375 (4th Cir. 2021); *Towns of Wellesley, Concord & Norwood, Mass. v. FERC*, 829 F.2d 275, 277 (1st Cir. 1987).

Under *TRAC*, courts consider the following factors "in assessing claims of agency delay":

> (1) the time agencies take to make decisions must be governed by a rule of reason;
>
> (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;
>
> (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
>
> (4) the court should consider whether expediting delayed action would affect agency activities of a higher or competing priority;
>
> (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and

(6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

*TRAC*, 750 F.2d at 80. Here, the second factor is neutral because Congress has not provided a timetable for DEA action. The remaining factors militate in favor of mandamus relief.

### A. Applying The Rule Of Reason, DEA's Delay Of More Than Four Years Is Unreasonable

The "most important factor" in the *TRAC* analysis is "that 'the time agencies take to make decisions must be governed by a rule of reason.'" *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008). Reasonableness "necessarily turns on the facts of each particular case." *Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987). And although "there is no *per se* rule as to how long is too long to wait for agency action, ... a reasonable time for agency action is typically counted in weeks or months, not years." *Am. Rivers & Idaho Rivers United*, 372 F.3d at 419 (internal citation omitted). So, "a reasonable time for an agency decision could encompass 'months, occasionally a year or two, but not several years.'" *Midwest Gas Users*, 833 F.2d at 359 (quoting *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 350 (D.C. Cir. 1980)).

DEA's four-year-plus delay in responding to Walmart's Petition is longer than many of the delays that courts have found unreasonable. *See, e.g., Pub. Citizen Health Rsch. Grp. v. Auchter,* 702 F.2d 1150, 1157-59 (D.C. Cir. 1983) (per curiam)

(three-year delay unreasonable); *MCI Telecomms.*, 627 F.2d at 324-25 (four-year delay unreasonable); *Families for Freedom*, 628 F. Supp. 2d 535 (two-and-one-half-year delay unreasonable); *Muwekma Tribe v. Babbitt*, 133 F. Supp. 2d 30, 37 (D.D.C. 2000) (two-year delay unreasonable).

DEA's failure to share when it intends to complete its review further reinforces the conclusion that the delay is unreasonable. *See Muwekma Tribe*, 133 F. Supp. 2d at 37. That is because an agency's silence on that score "defeats any assertion that the process proceeds with reasonable dispatch." *Id.* In the four years since Walmart filed the Petition, DEA has not said when it might respond to the Petition, even after further prodding from Walmart.[12] Thus, neither Walmart nor this Court can have any assurance that DEA is proceeding with reasonable diligence. As the D.C. Circuit has explained, "[t]here comes a point when relegating issues to proceedings that go on without conclusion in any kind of reasonable time frame is tantamount to refusing to address the issues at all and the result is a denial of justice." *MCI Telecomms.*, 627 F.2d at 344.

### B. The Interests At Stake, Including Harm To Human Health And Welfare, Support Granting The Writ.

The "nature and extent of the interests prejudiced by [DEA's] delay," including "human health and welfare," also weigh heavily in favor of mandamus

[12] Ex. 3.

relief. *TRAC*, 750 F.2d at 80. DEA's delay obscures pharmacists' legal obligations regarding particular pharmaceuticals at the center of a national public health crisis. And it contributes to the denial of patient access to opioids that are legitimately prescribed by registered doctors. Those harms amply support mandamus relief.

### 1. DEA's Delay Harms Pharmacists And Pharmacies By Prolonging The Imposition Of Conflicting And Often Contradictory Duties On Them.

As described below, DEA's refusal to promulgate a formal rule governing pharmacists' obligations with respect to the filling of facially valid opioid prescriptions written by DEA-registered doctors has left pharmacists in "administrative limbo." *Friedman v. FAA*, 841 F.3d 537, 545 (D.C. Cir. 2016). Today, pharmacists in the United States are caught between the shifting federal standards articulated by DEA and DOJ in litigation and through informal guidance on the one hand, and the conflicting demands of state regulators on the other. DEA and DOJ have not acknowledged this conflict, much less attempted to promulgate binding federal legal standards that would provide pharmacists with regulatory certainty.

The CSA imposes a statutory duty on pharmacists not to dispense controlled substances "without the written prescription of a practitioner," 21 U.S.C. § 829(a), and it also gives the Attorney General authority to promulgate "rules and regulations ... relating to the ... dispensing of controlled substances," 21 U.S.C. § 821. Tracking

the statute, those regulations first put "[t]he responsibility for the proper prescribing and dispensing of controlled substances … upon the prescribing practitioner." 21 C.F.R. § 1306.04(a). Then, they state that "a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* That corresponding responsibility entails not filling a prescription if the pharmacist "know[s]" it was issued by the prescriber outside "the usual course of professional treatment." *Id.* DEA added that strong scienter requirement of *knowledge* to address pharmacists' concerns about bearing "responsibility … to determine the legitimacy of a prescription." *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7,776, 7,777 (April 24, 1971). Additionally, DEA's regulations permit pharmacists to fill a prescription only while "acting in the usual course of ... professional practice." 21 C.F.R. § 1306.06. Although there are no cases construing the usual course standard with respect to pharmacists, the cases that deal with that standard as applied to physicians make clear that medical professionals are generally considered to have acted within the usual course.[13]

[13] *United States v. Moore*, 423 U.S. 122, 143 (1975) (Acting outside "the usual course" means no longer acting as a pharmacist "at all"—for example, by "act[ing] as a large-scale 'pusher.'"); *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006) (acting outside the usual course does not mean just acting as a "bad or negligent" medical professional); *see Ruan v. United States*, 597 U.S. 450, 479 (2022) (Alito, J., concurring in the judgment) (explaining that a prescriber leaves the usual course when he serves "[o]bjectives" that are "alien to medical practice," not when he "makes negligent or even reckless mistakes in prescribing drugs").

As DEA itself has emphasized, the decision to fill a particular prescription thus depends on the case-by-case professional judgment of a pharmacist. *See* DEA, *The Pharmacist's Manual* 39 (2020);[14] DEA, *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52,716, 52,719-52,720 (Sept. 6, 2006). And for over 50 years, DEA has promulgated no other regulations regarding the obligations of pharmacists when dispensing controlled substances.

But despite this minimal regulatory guidance, DOJ and DEA have threatened and carried out enforcement actions against pharmacy owners based on purported categorical duties that appear nowhere in the statute or regulations. For example:

- DOJ and DEA have stated that pharmacists must take special (but unspecified) actions to identify and resolve "red flags" that purportedly raise questions about whether a prescription serves a legitimate medical purpose.[15]

- DOJ and DEA have claimed that pharmacists must document the resolution of all red flags.[16]

- DOJ and DEA claim that large categories of prescriptions raise "unresolvable" red flags and cannot be filled in any circumstance. For instance, DOJ and DEA have suggested that (i) any prescription presented by a patient a certain number of days before the next regularly scheduled prescription and (ii) so-called "trinity" combinations of drugs—

[14] https://www.deadiversion.usdoj.gov/GDP/%28DEA-DC-046R1%29%28EO-DEA154R1%29_Pharmacist%27s_Manual_DEA.pdf.

[15] *See, e.g.*, Am. Del. Compl. ¶¶ 70-75; CVS Compl. ¶¶ 45-48, 105-106; Walgreens Compl. ¶¶ 79-95.

[16] *See, e.g.*, Am. Del. Compl. ¶¶ 8, 74, 90, 547, 556; CVS Compl. ¶¶ 45, 47-48, 113.

prescriptions that combine an opioid (for pain), a benzodiazepine (for anxiety), and a muscle relaxer—constitute unresolvable red flags.[17]

- DOJ and DEA have taken the position that "acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations"—no matter their nature.[18] In other words, every state-law pharmacy regulatory violation—even if subject only to minor (or no) state penalties—may give rise to a federal crime.

- According to DOJ and DEA, pharmacy owners must analyze and share information—including about a pharmacist's refusal to fill a particular prescription and the habits of doctors and patients—across stores. Under this theory, a corporation has duties far beyond those owed by individual pharmacists, including obligations to categorically block certain prescriptions based on (again unspecified) factors.[19]

Imposing liability based on those newfound unwritten duties is unlawful. Only "[r]ules issued through the notice-and-comment process ... have the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (internal quotation marks omitted). The only existing federal regulation that binds pharmacists is the prohibition on "knowingly" filling an invalid prescription. DEA has never imposed any other categorical obligation on pharmacists through notice-

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[17] Am. Del. Compl. ¶¶ 482, 508; *see also* CVS Compl. ¶ 341 (describing "trinity" prescriptions as raising "egregious red flags"); Walgreens Compl. ¶¶ 251-52 (describing "trinity" prescriptions and prescriptions filled early as "egregious red flags").

[18] Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020), ECF No. 1; *see also* Compl. ¶ 19, *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018 (E.D.N.C. Jan. 29, 2020), ECF No. 1; CVS Compl. ¶ 106.

[19] *See* Compl. ¶¶ 9-13, *White v. Rite Aid Corp.*, No. 1:21-cv-1239-CEF (N.D. Ohio March 3, 2023); Am. Del. Compl. ¶¶ 60-61.

and-comment rulemaking. DEA's regulations do not mandate how a pharmacist should decide when not to fill a facially valid prescription from an actively licensed and DEA-registered doctor, let alone when a pharmacist should investigate certain (unknown) indicators before taking (unspecified) actions on the prescription. No federal statute or regulation imports the varied pharmacy laws of every state, let alone with the requisite clarity. *See United States v. Turley*, 352 U.S. 407, 411 (1957) ("[I]n the absence of a plain indication of an intent to incorporate diverse state laws into a federal criminal statute, the meaning of the federal statute should not be dependent on state law."). Nor does the CSA or any implementing regulation require pharmacy owners to document or maintain information about refusals to fill, much less to analyze or share that information in a particular way.

DOJ and DEA's attempt to impose these restrictions outside the rulemaking process also thwarts "judicial review" of the pharmacists' purported obligations "because there is no final agency action to challenge." *Prometheus Radio Project v. FCC*, 824 F.3d 33, 52 (3d Cir. 2016). If the agencies had proceeded through rulemaking and thereby "afford[ed] interested persons notice and an opportunity to comment," they could have engaged in the "fair[]," "informed administrative decisionmaking" that the APA requires—and regulated parties could petition for judicial review of the agencies' results. *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979). Instead, DOJ has sought to enforce its guidance through litigation,

demanding deference for the government's novel positions. But as the Supreme Court has observed, "[i]t is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference." *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012). Simply put, the absence of clear rules is a "breakdown of the regulatory process." *Nader v. FCC*, 520 F.2d 182, 207 (D.C. Cir. 1975).

That breakdown "come[s] at significant expense to" regulated entities prejudiced by DEA's delay, especially because those entities answer to an array of other regulators. *Prometheus Radio Project*, 824 F.3d at 52. Indeed, the purported federal obligations propounded by DOJ and DEA stand in considerable tension with state regulatory requirements. Under those requirements, pharmacists may not interfere with the doctor-patient relationship by usurping the doctor's professional judgment—understandably so, because they are not doctors, do not examine or diagnose patients, and cannot access patients' medical records. *See, e.g.*, American Medical Association Resolution 218 (2013) (criticizing "inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions" as

"interference with the practice of medicine").[20] The pharmacist's limited knowledge cannot provide the tools needed to second-guess doctors' judgments about the appropriate dosing for particular patients or the necessity of particular combinations of medicines.

Pharmacists and pharmacies also lack the tools and authority to strip unscrupulous doctors of their prescribing privileges. Congress entrusted that role to DEA. Yet DOJ's Inspector General has documented DEA's significant and repeated failures to vet doctors before letting them prescribe opioids and to revoke the credentials of suspicious doctors.[21] Having fallen down on its own supervisory responsibilities over doctors, DEA essentially seeks to outsource those responsibilities to pharmacists and pharmacies while exposing those pharmacists and pharmacies to state-law liability for interference with the doctor-patient relationship.

In fact, when pharmacists and pharmacies refuse to fill opioid prescriptions, they are reprimanded, investigated, and even sued by state officials and litigants. In one instance, the President of the Texas Medical Board threatened to issue "cease

[20] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a13-resolutions_0.pdf.

[21] *See* Office of the Inspector General, U.S. Dep't of Justice, *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* 15-17, 21-26 (Sept. 2019 revised), https://oig.justice.gov/reports/2019/e1905.pdf.

and desist orders" against pharmacists who "change amounts of opioids prescribed" or "override" a physician's judgment, asserting that doing so constitutes practicing medicine without a license.[22] In another, Wisconsin's Board of Pharmacy issued an Administrative Warning to a Walmart pharmacy because it "informed a local clinic that the Pharmacy would no longer fill controlled substance prescriptions from that clinic due to concerns of overprescribing."[23] The Wisconsin Board claimed that "[t]he broad prohibition ... deterred pharmacists at the Pharmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order."[24] In the years and months preceding the filing of its Petition, complaints against Walmart and its pharmacists for refusing to fill opioid prescriptions had been filed with, or pursued by, numerous Boards of Pharmacy, including those in Alaska, Arkansas, Colorado, Idaho, Kansas, Maryland, Missouri, New Hampshire, Ohio, Oregon, Pennsylvania, Tennessee, West Virginia, and Wisconsin.[25]

Doctors and patients have also sued pharmacists and pharmacies for refusing to fill certain opioid prescriptions. Doctors have launched defamation lawsuits

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[22] Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752.

[23] Wisconsin Pharmacy Examining Board, Administrative Warning, Division of Legal Services and Compliance Case Number 17 PHM 095 (Dec. 6, 2018).

[24] *Id.*

[25] Ex. 1 at 10-11.

against pharmacy owners, claiming that the pharmacy's refusal to fill a suspicious prescription implied wrongly that the doctor engaged in professional malfeasance.[26] Doctors have also alleged that a pharmacy's efforts qualify as the unlawful practice of medicine and tortious interference with the prescriber's business.[27] For their part, patients have sued pharmacists and pharmacy owners for refusing to fill facially valid prescriptions.[28]

In one example, at the very moment that DOJ accused Walmart of preventing "pharmacists from blanket refusing to fill" prescriptions from "pill-mill prescribers," *see* Am. Del. Compl. ¶¶ 209-220, a Nevada physician sued Walmart (and other pharmacies) alleging that "Pharmacists are prohibited from issuing blanket refusals to fill." *See* Compl. ¶¶ 25, 42-51, *Reiner*, *supra* note 26, ECF No. 1. Other pharmacies and pharmacists find themselves in the same untenable position. *See,*

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[26] *See, e.g.*, *Yarus v. Walgreen Co.*, 738 F. App'x 94 (3d Cir. 2018); *Goulmamine v. CVS Pharmacy, Inc.*, 138 F. Supp. 3d 652 (E.D. Va. 2015); *Richardson v. CVS Caremark Corp.*, No. 1:18 CV 1308, 2018 WL 4189522 (N.D. Ohio Aug. 31, 2018); *Kahn v. Ariz. CVS Stores LLC*, No. 1 CA-CV 16-0333, 2017 WL 586398 (Ariz. Ct. App. Feb. 14, 2017).

[27] *See, e.g.*, Compl. ¶¶ 22–24, 32–33, *Leer v. Walmart Inc.*, No. 22-cv-1835 (S.D. Ind. Sept. 16, 2022), ECF No. 1-1; Am. Compl. ¶¶ 137–61, 167–74, *Michael D. Reiner, M.D., P.C. v. CVS Pharmacy, Inc.*, No. 22-cv-701 (D. Nev. Apr. 11, 2023), ECF No. 74.

[28] *See, e.g.*, Compl. ¶ 2, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020), ECF No. 1 (putative class action alleging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020) (similar).

*e.g.*, Temporary Restraining Order, *Hansen v. CVS Pharmacy, Inc.*, No. 2:21-cv-00092 (E.D. Ky. Aug. 11, 2021), ECF No. 14 (enjoining CVS "from refusing to fill prescriptions written" by a doctor the pharmacy had categorically blocked).

In light of these conflicting demands, pharmacists' and pharmacies' "interests are weighty ... and are harmed by [their] years-long wait" for clarity from DEA. *See Barrios Garcia v. U.S. Dep't of Homeland Sec.*, 25 F.4th 430, 451 (6th Cir. 2022).

### 2. DEA's Delay Harms Patients And The General Public By Jeopardizing Access To Needed Prescriptions.

Because "human health and welfare are at stake," DEA's delay is even "less tolerable." *Public Citizen Health Res. Grp. v. Auchter*, 702 F.2d 1150, 1157-58 (D.C. Cir. 1983). Refusing to fill a facially valid prescription from an actively licensed and DEA-registered doctor—as pharmacies have been forced to do to avoid liability under the shifting legal standards propounded by DEA and DOJ in guidance and litigation—raises special concerns because it threatens to override the doctor's professional judgment about patient care. Courts have held that much shorter delays than that at issue here were unreasonable when such health and welfare concerns were at stake. *See, e.g., Families for Freedom*, 628 F. Supp. 2d at 541. For instance, a court found that the Department of Homeland Security's "nearly two-and-one-half year delay" responding to a petition for "rulemaking regarding standards for detention facilities" was "egregious" because the delay "clearly implicate[d] concerns of human health and welfare." *Id.*

But unfilled prescriptions are just the tip of the iceberg with respect to patient welfare. DEA's foot-dragging perpetuates uncodified guidance that directly conflicts with the guidance of other federal, state, and national medical authorities responsible for studying and improving patient welfare. While DEA has advised pharmacists not to fill prescriptions that are "doubtful, questionable, or suspicious," DEA, *The Pharmacist's Manual* 42 (2020), patient advocates, medical and pharmaceutical boards, and even government agencies have cautioned pharmacists against disrupting the normal course of medical care in that manner, *see, e.g.*, American Medical Association Resolution 218, note 19, *supra*; p. 19, *supra*.

The CDC has long emphasized the need for "individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient." *CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain* (Apr. 24, 2019).[29] And, in November 2022, the CDC published new guidance that declines to adopt particular limits or directives and encourages doctors to use their "clinical judgment and individualized, patient-centered decision-making" to decide when to prescribe opioids, at what dosage, and for how long. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain* at

[29] https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.

4 (Nov. 4, 2022) ("2022 Guideline").[30] The 2022 Guideline emphasizes that CDC's recommendations "should not be applied as inflexible standards of care across patient populations by health care professionals; health systems; pharmacies; third-party payers; or state, local, or federal organizations or entities." *Id.* at 6. Rather, the Guideline references the "clinical, psychological, and social consequences" for patients "associated with pain," and reiterates that "it is important that clinicians consider *the full range* of pharmacologic and nonpharmacologic treatments for pain care." *Id.* at 2 (emphasis added).

Similarly, the Pain Management Best Practices Inter-Agency Task Force has endorsed "an individualized, patient-centered approach" while warning that "increased vigilance of prescription opioids and the tightening of their availability have in some situations led to unintended consequences such as patient abandonment and forced tapering," causing increased use of "illicit fentanyl and heroin." HHS, *Pain Management Best Practices Inter-Agency Task Force Report* 12, 17 (May 9, 2019) ("Task Force Report").[31] The FDA likewise advises that opioids "should not

[30] https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w; https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7103a1-H.pdf.

[31] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

[be] abruptly discontinue[d] ... in a patient who is physically dependent." *FDA Drug Safety Communication* (Apr. 9, 2019).[32]

The positions taken by DOJ and DEA—which would categorically forbid pharmacists from filling any prescription when certain "red flags" are present—conflict with the objective of an individualized approach. They induce pharmacists to decline to fill prescriptions that DEA-registered providers have deemed medically necessary under "evidence-based" guidelines and the provider's assessment. *See* 2022 Guideline at 2. Patients are the ones who suffer when valid prescriptions are not filled based on categorical limits. *Id.*

Worse yet, DEA's imprecise and conflicting positions have caused spillover effects as to other pharmaceuticals used to treat opioid addiction. Although classified as a synthetic opioid, buprenorphine is an opioid antagonist and is "widely used and encouraged" as a front-line treatment for opioid use disorder, particularly when paired with other interventions like counseling and behavioral changes. Task Force Report at 25. The Federal Substance Abuse and Mental Health Services Administration (SAMHSA) recognizes that buprenorphine is a key treatment for

[32] https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

opioid addiction,[33] and SAMHSA has taken steps to expand access for patients suffering from opioid use disorder. *See* Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 Fed. Reg. 22439 (Apr. 28, 2021); *see also* Task Force Report at 29 (characterizing "a lack of access to buprenorphine" as a "gap" and making recommendations to expand access).

Even DOJ and DEA themselves have highlighted the important role buprenorphine plays in treating opioid use disorder. In a March 2020 letter, DEA granted providers additional flexibility to prescribe buprenorphine for patients telephonically.[34] DEA also issued a letter praising Congress's bipartisan decision to end limits on the pool of practitioners qualified to prescribe buprenorphine on an outpatient basis.[35] DEA touted this "significant policy reform" as helping to

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[33] *See Certification of Opioid Treatment Programs (OTPs)*, https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program.

[34] Letter from DEA to Qualifying Practitioners Regarding Prescription of Buprenorphine During Public Health Emergency (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.

[35] *See Dr. Gupta Applauds Removal of X-Waiver in Omnibus, Urges Healthcare Providers to Treat Addiction* (Dec. 30, 2022), https://www.whitehouse.gov/ondcp/briefing-room/2022/12/30/dr-gupta-applauds-removal-of-x-waiver-in-omnibus-urges-healthcare-providers-to-treat-addiction/; Letter from A. Milgram, DEA to Registrants (Jan. 12, 2023), https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf.

"overcome opioid use disorder" by making buprenorphine "readily and safely available to anyone in the country who needs it."[36] DOJ has expressed similar views. In February 2022, DOJ argued that buprenorphine "improve[s] patients' health and wellness," and can be part of an "effective, evidence-based treatment" for opioid use disorder.[37]

But at the same time, DOJ and DEA have simultaneously used CSA enforcement to curb the dispensing of buprenorphine. For instance, in 2019, DEA obtained an emergency order (later dissolved by a reviewing court) suspending a West Virginia pharmacy's registration to distribute controlled substances because of its practices relating to buprenorphine prescriptions.[38] DEA claimed that the pharmacy violated the CSA by distributing buprenorphine to patients despite the presence of so-called "red flags," including that patients had traveled from out of state to obtain the medicine.[39]

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[36] *Id.*

[37] Compl. ¶¶ 9-12, 61, *United States v. The Unified Judicial System of Pennsylvania*, No. 2:22-cv-00709-MSG (E.D. Pa. Feb. 24, 2022), ECF No. 1; Am. Compl. ¶¶ 4-5, 24-29, 160-164, *United States v. The Unified Judicial System of Pennsylvania et al.*, No. 2:22-cv-00709-MSG (E.D. Pa. May 22, 2023), ECF No. 28 ("Am. Pa. Compl.").

[38] Mem. Opinion and Order, *Oak Hill Hometown Pharmacy v. Dhillon*, No. 2:19-cv-00716 (S.D.W.V. Oct. 30, 2019), ECF No. 17.

[39] *Id.* at 10-11.

Unsurprisingly, when Walmart and other pharmacies conform their conduct to the hazy standards propounded by DEA and DOJ, they are then accused of causing patients to suffer. For example, DOJ has alleged that Walmart acted unlawfully by filling prescriptions for buprenorphine in amounts that DOJ deemed "suspicious."[40] After Walmart responded to these enforcement efforts by curbing buprenorphine dispensing, medical authorities accused it of improperly refusing to dispense a prescription drug with known lifesaving benefits.[41]

Walmart sought formal rulemaking from DEA on these issues over four years ago precisely because it wished (and still wishes) to operate under a clear set of rules that may first be evaluated and commented upon by medical authorities and other stakeholders who can balance all relevant interests. But DEA refuses to act—and even refuses to say when it might act—on Walmart's Petition. DEA has offered no "justification for the considerable human health interests prejudiced by the delay." *In re Pesticide Action Network N. Am., Nat. Res. Def. Council, Inc.*, 798 F.3d 809, 814 (9th Cir. 2015). In such situations, courts have not hesitated to order the agency to act. *See, e.g.*, *Public Citizen*, 702 F.2d at 1157 (concluding that even with a

[40] Am. Del. Compl. ¶¶ 542, 731-735.

[41] Letter from Paul H. Earley, MD, President, American Society of Addiction Medicine to Thomas Van Gilder, MD, Chief Medical and Analytics Officer, Walmart, Inc. (Oct. 18, 2019), available at https://www.asam.org/docs/default-source/advocacy/101819-asam-letter-to-walmart_final-with-enclosuresdf432f9472bc604ca5b7ff000030b21a.pdf?sfvrsn=54ff4fc2_2.

projected issuance date, OSHA's delay of three years was "simply too long given the significant risk of grave danger" from workplace exposure to a toxic substance).

### C. Expediting DEA's Delayed Action Would Not Prejudice Agency Activities Of A Higher Or Competing Priority Because DEA Has Acknowledged The Urgency Of Clarifying Obligations Relevant To The Opioid Crisis.

Given DEA's intense focus on the opioid crisis, this is not a case where an agency should be given leeway based on its other activities. That *TRAC* factor "generally cautions against facilitating line-jumping and reordering agency priorities." *In re Center for Biological Diversity*, 53 F.4th at 672. For example, where a complainant sought an investigation from the Executive Office for Immigration Review, but the agency had "hundreds of pending complaints, many of which were received before [he] filed his complaint," granting his petition would merely put him "at the head of the queue." *Vaz v. Neal*, 33 F.4th 1131, 1138 (9th Cir. 2022). In the absence of such a backlog and when "the concerns raised ... are of the utmost importance," "expediting [a] decision" on whether and how to initiate rulemaking "surely would not interfere with any agency activities of higher or competing priority." *Families for Freedom*, 628 F. Supp. 2d at 541 (internal quotation marks omitted).

Here, there is no line to jump, and this Court need not reorder DEA's priorities to grant the modest relief Walmart seeks. DEA and DOJ have made clear that pharmacists' obligations are a priority given that DOJ has filed or participated in

multiple lawsuits against pharmacies. Along with suing Walmart and CVS for alleged failures to identify and investigate "red flags" and adopt various corporate policies, *see supra* at pp. 6-9, DOJ has sued other pharmacy owners across the country based on similar theories.[42] DOJ has highlighted those lawsuits in press releases as reflecting DOJ's "priority ... to hold accountable" those it believes are "responsible for the prescription opioid crisis."[43] And DOJ has filed *amicus* briefs in other cases trumpeting its sub-regulatory theories. *See, e.g.*, *In re Nat'l Prescription Opiate Litig.*, No. 22-3750, Brief for the United States as Amicus Curiae 9-10 (6th Cir. Mar. 21, 2023) (arguing violations occur when pharmacists fill prescriptions with what the government considers to be "significant indicia of invalidity," even if pharmacists lack "knowledge that the prescription is invalid"). If such obligations are important enough to warrant aggressive nationwide litigation, they are important enough for DEA to put in the Federal Register so that pharmacists can know their obligations, comply, and seek judicial review to the extent those

[42] *See, e.g.*, Complaint in Intervention, *United States v. Rite Aid Corp.*, No. 1:21-cv-1239 (N.D. Ohio, Mar. 13, 2023), ECF No. 38.

[43] DOJ, *Department of Justice Files Nationwide Lawsuit Against Walmart Inc. for Controlled Substance Act Violations*, https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act (Dec. 22, 2020); *see also* DOJ, *Department of Justice Files Complaint Alleging that Rite Aid Dispensed Controlled Substances in Violation of the False Claims Act and the Controlled Substances Act*, https://www.justice.gov/usao-ndoh/pr/united-states-files-complaint-alleging-rite-aid-dispensed-controlled-substances (Mar. 20, 2023); CVS Compl. ¶¶ 45-48.

requirements are unlawful. But even if DEA disagrees and thinks that rulemaking is unnecessary, it should at a minimum say so by denying Walmart's Petition.

Even assuming DEA has other important priorities, "the clear balance of the *TRAC* factors favors issuance of the writ" because DOJ and DEA have acknowledged a "clear threat to human welfare." *In re Nat. Res. Def. Council, Inc.*, 956 F.3d 1134, 1142 (9th Cir. 2020). Any additional agency priorities support "craft[ing] a remedy" that is appropriate, not denying one altogether. *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 553 (D.C. Cir. 1999); *see also In re Pub. Empls. for Envt'l Resp.*, 957 F.3d 267, 275 (D.C. Cir. 2020).

Because Walmart "does not ask [DEA] to promulgate any particular rule or policy," the relief it seeks from this Court is "neither technical nor intrusive." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 859 (D.C. Cir. 2008); *see also Mashpee Wampanoag Tribal Council, Inc.*, 336 F.3d at 1102 (a reasonable time for action depends on "the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency"). If DEA believes rules are unnecessary, it should not take years merely to "put its rationale in writing." *In re Core Commc'ns*, 531 F.3d at 859. And if DEA agrees that rules are necessary, it should grant the Petition and issue a notice of proposed rulemaking. What DEA cannot continue to do is refuse to give "*any* answer" in a "marathon round of administrative keep-away." *Am. Rivers & Idaho Rivers United*, 372 F.3d at 419-20.

## CONCLUSION

For the foregoing reasons, the Court should issue a writ of mandamus ordering the DEA to respond to Walmart's Petition within 30 days.

January 19, 2025

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

The foregoing petition is in 14-point Times New Roman proportional font and contains 7,308 words, and thus complies with the type-volume limitation set forth in Rules 21(d)(1), 32(a)(5) and 32(a)(6) of the Federal Rules of Appellate Procedure.

## CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2025, I caused one copy of the foregoing to be served on each of the following by certified United States mail, return receipt requested:

Office of the Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Office of the Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

/s/ Elbert Lin
Elbert Lin

# Exhibit 1

Akin Gump
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**PRATIK A. SHAH**
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November 24, 2020

Timothy J. Shea, Acting Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

**Re:** ***Rulemaking Petition To Clarify Obligations Of Opioid Dispensers Under The Controlled Substances Act***

Dear Mr. Shea:

Pursuant to section 553(e) of Title 5 of the U.S. Code, Walmart Inc. petitions the Drug Enforcement Administration for rulemaking regarding any legal duties that the Controlled Substances Act imposes on prescribing physicians, pharmacists, and pharmacy owners beyond those delineated in the Act and existing regulations. The company's petition is attached. All notices to be sent regarding this petition should be addressed to undersigned counsel for Walmart, whose address is included herein.

Thank you for your consideration.

Sincerely,

Pratik A. Shah
*Counsel for Walmart Inc.*

**PETITION FOR AGENCY RULEMAKING**

**SUBMITTED TO**
**THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION**
**NOVEMBER 24, 2020**

**To:**

Timothy J. Shea, Acting Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

**Submitted on behalf of Petitioner Walmart Inc. by:**

Pratik A. Shah
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## I. Overview

Amidst an unprecedented opioid crisis touching millions of lives, most pharmacists and pharmacy owners are doing their best to comply with legal obligations under the Controlled Substances Act ("CSA"), while respecting their obligations to patients, federal and state regulators, law enforcement agencies, and other actors. On November 2, 2020, the U.S. Drug Enforcement Administration ("DEA") published a notice of proposed rulemaking ("NPRM") setting forth the responsibilities of controlled-substance *distributors*. Statements and actions of DEA and Justice Department enforcement officials demonstrate the urgent need for DEA also to promulgate clear regulations—informed by broad public and expert input—setting forth the specific responsibilities of controlled-substance *prescribers* and the corresponding responsibilities of *dispensers*. Accordingly, Walmart Inc. files this petition for rulemaking.

Pharmacists have a professional duty to fill valid prescriptions. The CSA and existing regulations create two (and only two) circumstances in which pharmacists violate the CSA when filling facially valid prescriptions for controlled substances: (1) if they "knowingly fill[]" a prescription that was not issued by a doctor "in the usual course of professional treatment," 21 C.F.R. § 1306.04(a), and (2) if they fill a prescription outside the "usual course of" pharmacy practice, *id.* § 1306.06. The CSA regulations charge "prescribing practitioner[s]" registered with DEA with the primary "responsibility" for proper dispensing of controlled substances, while conferring on pharmacists a "corresponding" duty that depends on their case-by-case judgment in filling individual prescriptions (without the benefit of a medical license, examining the patient, or access to medical records). *Id.* § 1306.04(a). The role a pharmacist plays thus necessarily depends on the conduct and responsibilities of other actors in the system, including the prescribing physicians (in exercising their own sound medical judgment); state medical boards (in licensing

physicians and approving or prohibiting medical practices); and DEA itself (in registering physicians and revoking the credentials of problematic prescribers).

Despite the seemingly clear-cut allocations of responsibilities in those CSA regulations, pharmacists and pharmacy owners are buffeted by demands and threats of DOJ and DEA, on the one hand, and state medical licensing boards, medical associations, and individual litigants, on the other. The demands DOJ and DEA now seek to impose on pharmacists and pharmacies find no support in the text of the CSA or its regulations; instead, the agencies are seeking to enforce sub-regulatory expectations that pharmacists and pharmacies interfere in the doctor-patient relationship to a degree not contemplated by the CSA. For example, in an atmosphere of increased DOJ and DEA pressure, Walmart took a number of voluntary steps to address certain opioid prescription practices. As a result, Walmart was met with state investigations and lawsuits for interfering with medical practice—that is, for going *too far* in refusing to fill opioid prescriptions. At the same time, DOJ and DEA have threatened to sue Walmart for not going *far enough* in refusing to fill opioid prescriptions—including for continuing to fill opioid prescriptions of licensed physicians still authorized by DEA to prescribe opioids to this day. Indeed, DOJ and DEA enforcement and threatened enforcement of sub-regulatory expectations are contributing to a variety of significant and ongoing legal and policy conflicts among federal agencies, and between federal and state regulators, about the proper role of pharmacists and pharmacies in dispensing controlled substances prescriptions.

Rather than enforce shifting sub-regulatory expectations that contradict the expert guidance of federal and state health regulators, DEA should initiate notice-and-comment rulemaking to provide prescribers, pharmacists, and pharmacies with the advance notice and clarity they need to comply with any CSA obligations. By involving the public and health experts to help clarify the

obligations of these actors, a rulemaking would result in a better informed and more effective approach to managing the opioid epidemic. Not only pharmacists but all actors in the chain of prescription administration—as well as federal and state regulators, patients, and the general public—would benefit from the clarity a rule would provide. DEA should grant this petition for rulemaking.

## II. Statement of Interest

Although Walmart is not principally a pharmacy, the company operates more than 5,000 in-store pharmacies nationwide. Walmart's pharmacies help serve the needs of a diverse array of local communities and—as a component of Walmart stores—offer one-stop shopping for customers. Walmart's pharmacy operations also disproportionately help those with limited financial resources. Each year, Walmart fills prescriptions for millions of customers on Medicare, Medicaid, and TRICARE (the insurance system for military personnel, veterans, and their families). Nearly half of the prescriptions filled at Walmart pharmacies are paid for by one of these programs.

Walmart's pharmacy dispensing policies have always complied with the letter and spirit of the CSA. Above all, Walmart has consistently supported its pharmacists in the discharge of their duties. Walmart has long encouraged its pharmacists to exercise their professional judgment and to refuse to fill opioid prescriptions that they do not believe to be valid. In fact, Walmart pharmacists have refused to fill hundreds of thousands of opioid prescriptions. Walmart also has adopted innovative opioid-stewardship programs and partnered with law enforcement agencies, including DEA, to help root out corrupt doctors and put them behind bars. Despite these efforts, DOJ has stated it will file a civil complaint against Walmart for filling prescriptions with certain "red flags," not categorically refusing to fill certain prescriptions, and not altogether blocking prescriptions from certain doctors (even hundreds still licensed by the DEA). At the same time,

Walmart has been met with inquiries, lawsuits, threats, and investigations from doctors, patients, legislators, and state boards of medicine and pharmacy on the ground that Walmart's actions in blocking dispensing of prescription opioids interfere with the doctor-patient relationship. *See* Eric Felten, *Walmart an Opioid Villain? The Curious Case of a Deep-Pocketed Defendant*, REALCLEAR INVESTIGATIONS (Oct. 23, 2020), *available at* https://www.realclearinvestigations.com/articles/2020/10/23/a_big_culprit_in_opioids_legal_reckoning_is__wait__walmart_125734.html.

The irreconcilable demands faced by Walmart, the thousands of pharmacists it employs, and other pharmacies and pharmacists demonstrate the need to promulgate rules setting forth the specific legal responsibilities of physicians, pharmacists, and pharmacy owners as they relate to prescriptions for opioids and other controlled substances. Walmart believes that initiating a notice-and-comment rulemaking proceeding is both appropriate and necessary in the midst of ongoing uncertainty during an unprecedented nationwide opioid crisis.

## III. Under Existing Law, Prescribers Have The Primary Duty To Ensure The Proper Administration of Controlled Substances By Writing Valid Prescriptions, While Pharmacists Owe A Corresponding Duty Not To Knowingly Fill Invalid Prescriptions

Under the statutory and regulatory framework governing the dispensing of controlled substances, the duty is on prescribers—*i.e.*, physicians—to ensure the proper administration of controlled substances through the writing of valid prescriptions. The duty of pharmacists is secondary: they may not *knowingly* fill *invalid* prescriptions written by physicians.

The CSA prohibits "any person . . . who is subject to the requirements of part C to . . . dispense a controlled substance in violation of section 829 of this title." 21 U.S.C. § 842(a)(1). Section 829, in turn, provides that no controlled substance "may be dispensed without the written prescription of a practitioner," *id.* § 829(a)—a requirement that "ensures patients use controlled substances under the supervision of a doctor." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). The CSA is thus concerned with ensuring that a properly licensed and registered doctor has

authorized the use of the controlled substance through a written prescription. Nothing in the statute restricts a duly registered and licensed pharmacist from dispensing controlled substances under a facially valid prescription.

DEA has promulgated regulations related to the prescribing and dispensing of prescriptions for controlled substances by prescribers and pharmacists. Many of these requirements are technical—*e.g.*, a licensed and registered practitioner must write the prescription, *see* 21 C.F.R. § 1306.03(a); it must "be dated as of, and signed on, the day when issued"; and it must include certain information, such as "the drug name, strength, dosage form, quantity prescribed, [and] directions for use," *id.* § 1306.05(a). Under some circumstances, however, a physician's prescription that meets these technical specifications may still be invalid, in which case it "is not a prescription at all for purposes of the statute." *United States v. Hayes*, 595 F.2d 258, 260-261 (5th Cir. 1979). Two regulations outline those circumstances.

The principal regulation defining a valid "prescription" and (to a limited extent) setting forth the duties of prescribers and pharmacists, 21 C.F.R. § 1306.04(a), provides:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The first sentence of this regulation defines a valid prescription: The doctor must issue it for "a legitimate medical purpose" "in the usual course" of his practice. *Id.* The second allocates responsibility for ensuring adherence to that rule: The primary duty falls "upon the prescribing practitioner," but the pharmacist also holds a "corresponding responsibility." *Id.* The third

sentence spells out how those responsibilities operate in practice and their implications: A "purported prescription" issued outside "the usual course of professional treatment" is not a prescription under 21 U.S.C. § 829, and "the person issuing it" (the doctor) and "the person *knowingly* filling" it (the pharmacist) are both "subject to the penalties provided for violations" of the CSA. *Id.* (emphasis added). Thus, a pharmacist violates the CSA based on this regulation only if (1) the prescriber did not issue prescriptions "for a legitimate medical purpose," and (2) the pharmacist filled them "knowing that the prescriptions were invalid." *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994).

The second regulation, 21 C.F.R. § 1306.06, states that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." The Supreme Court has explained that acting outside "the usual course" of one's profession means abandoning all professional norms to the point of no longer acting in a professional capacity, such as when a doctor "did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded." *United States v. Moore*, 423 U.S. 122, 143 (1975). In that case, the doctor also "did not charge for medical services rendered, but graduated his fee according to the number of tablets desired." *Id*. Because "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician," his activities "f[e]ll outside the usual course of professional practice" and subjected him to CSA liability. *Id*. at 124, 143. The meager case law applying section 1306.06 is in accord. *See United States v. Williams*, 416 F. Supp. 611, 613 (D.D.C. 1976) (pharmacist "must have known that some of the prescriptions had been forged . . . and that the bulk of them had not been issued in the course of legitimate medical practice"); *United States v. Barbacoff*, 416 F. Supp. 606, 609 (D.D.C. 1976) (pharmacist filled prescriptions "knowing that the signatures thereon were mechanically reproduced").

DEA has promulgated no other regulations regarding the obligations of pharmacists when dispensing controlled substances like opioids. Current law therefore forbids a pharmacist from knowingly filling a prescription issued by a prescribing physician outside the ordinary course of medical practice, or from dispensing outside the usual course of pharmacy practice—nothing more, nothing less. As DEA has itself emphasized, the decision to fill a particular prescription thus depends on the case-by-case judgment of licensed medical professionals. *See* DEA, The Pharmacist's Manual 42 (2020).

## IV. DOJ Has Threatened Enforcement Based On Purported Duties Found Nowhere In The CSA Or Its Regulations, In Conflict With Other Federal Guidance And State Standards

Although the CSA and its implementing regulations place only limited legal obligations on pharmacists—do not knowingly fill an invalid prescription or abandon all professional norms—DOJ and DEA are threatening legal action based on a much broader set of supposed duties found nowhere in the CSA or any regulation:

- *First*, DOJ and DEA have stated that pharmacists must take special (but unspecified) actions regarding prescriptions that raise what DEA calls "red flags"—factors that, according to DEA, might prompt questions about whether the prescription serves a legitimate medical purpose. DOJ has asserted not only that pharmacists and pharmacies must proactively identify such red flags and resolve them before filling a prescription, but also that they must document that resolution.

- *Second*, DOJ and DEA claim that large categories of prescriptions raise "unresolvable" red flags and simply cannot be filled by a pharmacist in any circumstance. For instance, DOJ and DEA have suggested that any prescription presented by a patient a certain number of days before the next regularly scheduled refill constitutes a red flag that can never be resolved, and that so-called "trinity" combinations of drugs—prescriptions that combine an opioid (for pain), a benzodiazepine (for anxiety), and a muscle relaxer—may also constitute unresolvable red flags.

- *Third*, DOJ and DEA have taken the extraordinary and unprecedented position that "acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations"—no matter its nature. Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. filed Oct. 30,

2020), ECF No. 1; *see also* Compl. ¶ 19, *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018 (E.D.N.C. filed Jan. 29, 2020), ECF No. 1. In other words, every state regulatory or administrative violation—which may be subject only to minor penalties, or even no penalties at all, under state law—gives rise to a CSA violation and potentially to a *federal crime*.

- *Finally*, according to DOJ and DEA, pharmacy owners like Walmart are required to analyze and share information—including information about a particular pharmacist's refusal to fill a particular prescription and the prescribing and prescription-filling habits of particular doctors and patients—across all of its stores. Under this theory, the corporation that employs a pharmacist has duties extending far beyond those owed by the individual pharmacist, including obligations to categorically block prescriptions written by particular doctors based on (again unspecified) factors.

Imposing liability on pharmacists or pharmacy owners based on such alleged requirements—far beyond those specified in any statute or regulation—would be unlawful. Congress may authorize agencies to promulgate regulations carrying the force and effect of law, and agencies can then enforce those regulations. But only "[r]ules issued through the notice-and-comment process . . . have the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (internal quotation marks omitted). And no such rule imposes the above duties. Current DEA regulations impose no categorical obligations (beyond not "knowingly" filling an invalid prescription) and little practical advice on how a pharmacist should go about deciding when not to fill a facially valid prescription from an actively licensed and DEA-registered doctor. Neither the CSA itself nor section 1306.04(a) mentions any specific indicators that a prescription is or may not be valid. They neither specify when such indicators (or any combination of them) would prohibit a pharmacist from filling the prescription nor suggest that a pharmacist must investigate certain indicators before proceeding. No statute or regulation imports the varied pharmacy laws of every state, let alone with the requisite level of clarity. *See United States v. Turley*, 352 U.S. 407, 411 (1957) ("[I]n the absence of a plain indication of an intent to incorporate diverse state laws into a federal criminal statute, the meaning of the federal statute should not be

dependent on state law."). Nor does the CSA or any regulation require pharmacy owners to document or maintain any information about refusals to fill, much less to analyze or share that information in a particular way. In other words, no legally enforceable provision imposes the above restrictions on pharmacies or pharmacists.

What is more, those extra-legal obligations go beyond what pharmacists are trained and licensed to perform. And they conflict with the requirements of state regulators who oversee the practice of pharmacy and medicine. By law, pharmacists presented with a valid opioid prescription cannot interfere with the doctor-patient relationship by usurping the doctor's professional judgment—and understandably so, because they are not doctors, do not examine or diagnose patients for purposes of dispensing opioid medications, and do not have access to patients' medical records. Instead, a pharmacist's knowledge of the situation is generally limited to the four corners of the prescription, the patient's history at that particular pharmacy, any of the patient's information viewed by the pharmacist in the state Prescription Drug Management Program, a brief interaction with the patient, and any follow-up or inquiry that the pharmacist may conduct by contacting the prescribing doctor's office. Pharmacists accordingly lack the tools needed to second-guess doctors' judgments about questions that remain vigorously debated in the medical field (and even within the government's law enforcement and health agencies), such as the appropriate dosing for particular patients or the necessity of particular combinations of medicines.

When a patient presents a facially valid prescription from an actively licensed and DEA-registered doctor, refusing to fill the prescription raises special concerns because it overrides a licensed and registered doctor's professional judgment about the care and treatment of that doctor's patient. Thus, while DEA has recently advised pharmacists *not* to fill prescriptions that are "doubtful, questionable, or suspicious," DEA, The Pharmacist's Manual 42 (2020), patient

advocates, medical and pharmaceutical boards, and even government agencies have cautioned pharmacists against disrupting the normal course of medical care in that manner. That holds true for prescription opioids, which "should not [be] abruptly discontinue[d] . . . in a patient who is physically dependent." FDA, FDA Drug Safety Communication (Apr. 9, 2019), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

In fact, when they refuse to fill opioid prescriptions, pharmacists and pharmacy owners have been reprimanded, investigated, and even sued. In one instance, the President of the Texas Medical Board threatened to issue "cease and desist orders" against pharmacists who "change amounts of opioids prescribed" or "override" a physician's judgment, asserting that doing so constitutes practicing medicine without a license. Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752. In another, Wisconsin's Board of Pharmacy threatened disciplinary action, issuing an Administrative Warning to a Walmart pharmacy because it "informed a local clinic that the Pharmacy would no longer fill controlled substance prescriptions from that clinic due to concerns of overprescribing." Wisconsin Pharmacy Examining Board, Administrative Warning, Division of Legal Services and Compliance Case Number 17 PHM 095 (Dec. 6, 2018). The Wisconsin Board claimed that "[t]he broad prohibition . . . deterred pharmacists at the Pharmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order," and warned that "any subsequent similar violation may result in disciplinary action." *Id.* The Tennessee Board of Pharmacy similarly has investigated whether Walmart's refusals to fill prescriptions violate state law, and has complained about interference by corporate headquarters with the professional judgment of pharmacists. Altogether, complaints against Walmart and its pharmacists

for refusing to fill opioid prescriptions have been filed with, or pursued by, numerous Boards of Pharmacy, including those in Alaska, Arkansas, Colorado, Idaho, Kansas, Maryland, Missouri, New Hampshire, Ohio, Oregon, Pennsylvania, Tennessee, West Virginia, and Wisconsin.

Pharmacists also have been investigated by state attorneys general and consumer protection officials when patients file complaints with the state after the pharmacist refuses a prescription. And doctors have launched defamation lawsuits against pharmacy owners for refusing to fill their prescriptions and thus implying that the doctor has engaged in professional malfeasance. *See, e.g.*, *Yarus v. Walgreen Co.*, 738 F. App'x 94 (3d Cir. 2018); *Goulmamine v. CVS Pharmacy, Inc.*, 138 F. Supp. 3d 652 (E.D. Va. 2015); *Richardson v. CVS Caremark Corp.*, No. 1:18 CV 1308, 2018 WL 4189522 (N.D. Ohio Aug. 31, 2018); *Kahn v. Ariz. CVS Stores LLC*, No. 1 CA-CV 16-0333, 2017 WL 586398 (Ariz. Ct. App. Feb. 14, 2017). Even patients have sued pharmacists and pharmacy owners for refusing to fill facially valid prescriptions, both in individual suits and in class action lawsuits under the Americans with Disabilities Act and analogous state laws. *See, e.g.*, Compl. ¶ 2, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020), ECF No. 1 (putative class action alleging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020) (similar).

All of this puts pharmacists and pharmacy owners in an untenable position. A pharmacist who follows the dictates of the professional licensing board and defers to the medical judgment of the prescribing, validly licensed, actively DEA-registered doctor risks civil or even criminal liability at the hands of the federal government if some of the prescriptions written by that doctor are later determined by DEA to be invalid. But a pharmacist who refuses to fill a prescription—even where so-called "red flags" are present—risks other serious professional and personal

consequences: investigation by the state medical board, a lawsuit from the doctor, and more. Patients with medical needs are caught in the middle.

## V. DEA Should Grant This Petition And Initiate Rulemaking To Specify The Duties That Prescribers, Pharmacists, And Pharmacy Owners Owe Under The Controlled Substances Act

### 1) The Scope Of Opioid Dispensers' Legal Duties Is A Textbook Example Of An Issue That Would Benefit From Notice-And-Comment Rulemaking

The current predicament faced by pharmacists and pharmacy owners—among others, including doctors and patients—cries out for rulemaking by DEA. As explained above, no existing regulation imposes any of the specific expectations that DOJ and DEA have threatened to enforce against pharmacists and pharmacies. Moreover, the agencies' sub-regulatory expectations frequently conflict with the legal and policy judgments of federal and state health agencies. Notice-and-comment rulemaking will standardize dispensing practices and recordkeeping with respect to controlled substance prescriptions; clarify the respective responsibilities of prescribing physicians, pharmacists, and pharmacy owners; and afford all regulated actors the certainty they need to proceed in this challenging area.

The APA "was designed to promote general fairness and regularity in administrative action." *Pan-Atlantic S.S. Corp. v. Atlantic Coast Line R.R. Co.*, 353 U.S. 436, 442-443 (1957). To that end, it mandates specific "procedural requirements which 'assure fairness and mature consideration of rules of general application.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (quoting *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969) (plurality op.)); *see MCI Telecommc'ns Corp. v. FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995) (APA procedures designed to encourage "public participation and fairness to affected parties"). Those procedural requirements ensure that legislative rules—*i.e.*, ones "affecting individual rights and obligations"—are

promulgated only after "certain procedural requisites" are satisfied. *Chrysler*, 441 U.S. at 301-302.

Chief among these procedural safeguards is the right of the public to notice and participation before an agency enacts legislative rules with binding effect. "In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." *Chrysler*, 441 U.S. at 316. That "relatively formal administrative procedure tend[s] to foster the fairness and deliberation that should underlie a pronouncement" with the force of law. *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001); *see Small Refiner Lead Phase-Down Task Force v. U.S.E.P.A.*, 705 F.2d 506, 547 (D.C. Cir. 1983) (observing that "notice and the opportunity to be heard are an essential component of 'fairness to affected parties'"). Unlike adjudications, which "by nature are likely to be specific to individuals or entities," rulemaking scenarios "generally involve broad applications of more general principles." *Neustar, Inc. v. FCC*, 857 F.3d 886, 893, 896 (D.C. Cir. 2017). Although "[a]djudicated cases may . . . serve as vehicles for the formulation of agency policies, . . . this is far from saying . . . that commands, decisions, or policies announced in adjudication are 'rules' in the sense that they must, without more, be obeyed by the affected public." *Wyman-Gordon Co.*, 394 U.S. at 765-766 (plurality op.) (footnote omitted).

Beyond fairness, notice-and-comment rulemaking has a number of other benefits. For one, it "improves the quality of agency rulemaking by ensuring that agency regulations will be 'tested by exposure to diverse public comment.'" *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547. By inviting public participation, notice-and-comment requirements "assure that the agency

will have before it the facts and information relevant to a particular administrative problem." *MCI Telecommc'ns Corp.*, 57 F.3d at 1141 (internal quotation marks omitted).

Indeed, the benefits of broad public participation are particularly apparent in a complex situation (like this one) where so many "important interests are in conflict." *Chrysler*, 441 U.S. at 316. The "opioid threat (controlled prescription drugs, synthetic opioids, and heroin) continues at ever-increasing epidemic levels, affecting large portions of the United States." DEA, 2019 National Drug Threat Assessment 4, *available at* https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf. DEA rules governing controlled substance prescriptions thus affect the interests of a broad array of parties: pharmacists, pharmacy owners, doctors, nurses, patients, hospitals, clinics, state medical boards, medical associations, and federal, state, and local law enforcement, to name a few. Formal rulemaking with public participation is crucial to ensure that DEA properly "strike[s] a balance" in allocating responsibilities among such a multitude of stakeholders. *Chrysler*, 441 U.S. at 316.

In addition to promoting sound decisionmaking, notice-and-comment rulemaking leads to clear rules for regulated parties and helps avoid retroactivity concerns. Especially when an agency has the power to bring enforcement actions, as here, it "should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires.'" *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (alteration in original) (quoting *Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986)); *see, e.g.*, *Phelps Dodge Corp. v. Federal Mine Safety & Health Review Comm'n*, 681 F.2d 1189, 1192 (9th Cir. 1982) ("[T]he application of a regulation in a particular situation may be challenged on the ground that it does not give fair warning that the allegedly violative conduct was prohibited."); *Kropp Forge Co. v. Secretary of Labor*, 657 F.2d 119, 122 (7th Cir. 1981) (refusing to impose sanctions where

standard the regulated party allegedly violated "d[id] not provide 'fair warning' of what is required or prohibited"); *Diamond Roofing Co. v. Occupational Safety & Health Review Comm'n*, 528 F.2d 645, 649 (5th Cir. 1976) ("[S]tatutes and regulations which allow monetary penalties against those who violate them" must "give an employer fair warning of the conduct [they] prohibit[] or require[.]"). Crafting binding legislative obligations through notice-and-comment rulemaking thus offers advance notice to regulated parties and avoids "unfair surprise." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170-171 (2007); *see Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 158 (1991) (identifying "adequacy of notice to regulated parties" as one factor relevant to the reasonableness of the agency's interpretation).

By contrast, fashioning and enforcing obligations through interpretations of ambiguous statutory or regulatory language found only in sub-regulatory guidance or post hoc, case-by-case adjudication "frustrat[es] the notice and predictability purposes of rulemaking." *Christopher*, 567 U.S. at 158; *see NLRB v. Bell Aerospace Co. Div. of Textron Inc.*, 416 U.S. 267, 295 (1974) (an agency should avoid imposing "new liability . . . on individuals for past actions which were taken in good-faith reliance on [agency] pronouncements" or in a case involving "fines or damages"). As the Supreme Court has observed, "[i]t is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference." *Christopher*, 567 U.S. at 158-159. Indeed, one of the reasons courts defer to an agency's interpretation of its own regulations is that the agency's interpretation "itself never forms the basis for an enforcement action." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (plurality

op.). "An enforcement action must instead rely on a legislative rule, which (to be valid) must go through notice and comment." *Id.*

All of the foregoing principles should be non-controversial. In fact, DOJ has acknowledged them repeatedly and recently: "Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents," which "cannot by themselves create binding requirements that do not already exist by statute or regulation." Justice Manual § 1-20.100 (Dec. 2018); *see* 28 C.F.R. § 50.27 (same). That provision implements an Attorney General directive stating that "guidance may not be used as a substitute for rulemaking." Memorandum of Att'y Gen. Jefferson B. Sessions III, Prohibition on Improper Guidance Documents (Nov. 16, 2017), *available at* https://www.justice.gov/opa/press-release/file/1012271/download. DOJ has since codified that requirement in a binding regulation. *See* Interim Final Rule, Processes and Procedures for Issuance and Use of Guidance Documents, 85 Fed. Reg. 63,200 (Oct. 7, 2020) (to be codified at 28 C.F.R. pt. 50). Under that regulation, DOJ cannot "treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations." 28 C.F.R. § 50.27(b)(1). Rather, "[t]he Department must establish a violation by reference to statutes and regulations." *Id*.

The necessity of specific regulations for those doctors and pharmacists who administer and dispense controlled substances is underscored by DEA's recent promulgation of guidance for those who *distribute* such substances. Just weeks ago, DEA issued an NPRM regarding regulations for distributors related to "Suspicious Orders and the Opioid Epidemic." *See* Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, 85 Fed. Reg. 69,282 (proposed Nov. 2, 2020) (to be codified at 21 C.F.R. pt. 1301). As most relevant here, DEA

"propos[ed] to amend its regulations to provide registrants with additional clarity regarding the procedures that must be followed upon receiving an order under suspicious circumstances." *Id.* at 69,288. Among other things, DEA proposed to add a number of specific definitions, as well as to identify specific "procedures for identifying and reporting suspicious orders of controlled substances consistent with the due diligence requirement articulated in" various agency adjudications. *Id.* DEA described "numerous non-quantifiable benefits associated with this rule," including to "provide[] clarity and enhance[] understanding of required procedures," "formalize current business practices and create consistency across all registrants," and "standardize reporting procedures." *Id.* at 69,292; *see id.* at 69,285 (describing regulation as "the next step to address suspicious orders and combat the opioid epidemic"). But this proposed rule explicitly "does not apply to controlled substances dispensed or administered within the normal course of professional practice of a practitioner, to include prescriptions filled by a pharmacy." *Id.* at 69,289

This petition for rulemaking thus seeks clarity for the benefit of regulated actors that *prescribe* and *dispense* rather than distribute. That is, the ultimate goal of this petition is a rule that will "standardize" and "enhance[] understanding of required procedures," increase "efficiency," and provide much-needed "clarity regarding the procedures that must be followed" by pharmacists, pharmacy owners, and doctors in the context of prescriptions for controlled substances including opioids. 85 Fed. Reg. at 69,288, 69,292.

2) <u>DEA's Rulemaking Should Address Topics That Will Clarify The Legal Obligations Of Prescribers, Pharmacists, And Pharmacy Owners</u>

Clarity for prescribers, pharmacists, and pharmacies is urgently needed. As noted, existing CSA regulations related to pharmacists and doctors, sections 1306.04(a) and 1306.06, prohibit pharmacists from filling only those prescriptions they "know[]" to be invalid on a prescription-by-prescription basis (not categorically), and impose no specific investigative requirements on

pharmacists or pharmacy owners. To the extent DEA believes that prescribers and pharmacists should have additional duties beyond those delineated in existing regulations, then DEA should grant this petition and initiate a notice-and-comment rulemaking to impose those duties. Indeed, all actors in the chain of prescription administration—as well as patients, hospitals, federal and state regulators, the public at large, and many others—would benefit from such a rulemaking, and deserve to weigh in before DEA takes further action.

In particular, DEA's rulemaking proceeding should address at least the following issues related to doctor, pharmacist, and pharmacy owner responsibilities under the CSA in the context of writing or dispensing opioid prescriptions:

**1) The obligations of a pharmacist relative to those of a prescribing physician.**

Existing CSA regulations provide that the "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. 1306.04(a). State regulations provide the same, limiting the pharmacist's role and ability to second-guess a doctor's professional judgment about the care and treatment of the doctor's particular patient. To the extent DEA believes that the "corresponding" duty of a pharmacist should extend beyond refusing to "knowingly" fill invalid prescriptions, *id.*, it can extend that corresponding duty only through a new rulemaking. Any such rulemaking should address the specific nature of the pharmacist's obligations relative to the duty of the "prescribing practitioner." Indeed, because a pharmacist's responsibility is only "corresponding" to the duties of the "prescribing practitioner," any clarification or extension of a pharmacist's "corresponding" duty when *dispensing* controlled substances necessarily depends on first clarifying and extending the scope of the responsibilities

of practitioners when *prescribing* controlled substances. The rulemaking should address issues such as:

- whether and in what specific circumstances a pharmacist has a duty under the CSA to investigate, or refuse to fill, a facially valid prescription issued by a licensed and DEA-registered prescribing practitioner;

- whether and in what specific circumstances a pharmacist is subject to CSA liability when lacking knowledge, or even clear notice, that a prescription was not issued for a legitimate medical purpose by the DEA-registered practitioner; and

- whether and in what specific circumstances a pharmacist has the authority and duty to refuse to fill entire categories of prescriptions, regardless of the individual facts, even when issued by a DEA-registered practitioner in the usual course of professional medical practice.

**2) The obligations of a prescriber or a pharmacist to identify, investigate, document, and otherwise act on "red flags" or other indicia beyond the four corners of a facially valid prescription.**

Existing CSA regulations provide that pharmacists shall be liable only for "knowingly filling" a prescription not issued "in the usual course of professional treatment or in legitimate and authorized research." 21 C.F.R. 1306.04(a). Under that regulation, the prescriber bears the responsibility to issue a valid prescription in the first instance, and then the decision to fill a prescription depends on the pharmacist's sound professional judgment as to the validity of the prescription. To the extent DEA believes that pharmacists should have additional duties, it can enforce those new duties only if they are established in a rulemaking and are consistent with the CSA. If DEA believes it should impose such new obligations on pharmacists, it should do so through a rulemaking that addresses the duties of both prescribers and pharmacists with respect to "red flags," including:

- what categories of "red flags" or other indicia, if any, trigger a prescriber's duty under the CSA to refuse to write a prescription, including the weight to ascribe to any particular red flag or combination thereof;

- to what extent, if any, prescribers must document how certain "red flags" or other indicia of potentially problematic prescriptions have been resolved;

- to what extent, if any, prescribers have a duty under the CSA to cooperate with pharmacists seeking to investigate possible "red flags" about prescriptions;

- what duties, if any, pharmacists have under the CSA beyond the existing obligation to refuse to fill prescriptions they "know[]" to be invalid;

- what categories of "red flags" or other indicia, if any, trigger a pharmacist's duty under the CSA to question the validity of a prescription issued by a DEA registrant pursuant to a doctor-patient relationship, including the weight to ascribe to any particular flag or combination thereof;

- what process a pharmacist must follow, if any, including what investigative steps must be taken and what resolution is appropriate after any "red flags" are identified; and

- to what extent, if any, pharmacists must document "red flags" or other indicia, including any resolution of the same.

**3) The extent to which violations of state medical or pharmacy licensing rules trigger federal CSA liability.**

Existing CSA regulations provide that "[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Moreover, such a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice." *Id.* § 1306.06. To the extent DEA believes that compliance with "the usual course" of the relevant "professional practice" should turn on the prescriber's or pharmacist's compliance with applicable *state* laws and regulations, the rulemaking should address:

- which state rules, if violated, can form the basis of liability under the CSA;

- how CSA liability is affected by the nature of the predicate violation, including the extent, materiality, and procedural finality of any alleged or adjudicated noncompliance with a state law, regulation, or licensing requirement; and

- whether CSA liability is affected when the non-compliance with state rules is subject to minor, *de minimis,* or no penalties under state law.

**4) The obligations of a pharmacy business or owner.**

Existing CSA regulations do not identify any independent legal duties of a pharmacy business or owner related to the filling of opioid prescriptions. To the extent DEA believes a pharmacy business or owner should have specific duties beyond the duties owed by an individual pharmacist employee, the rulemaking should address:

- the nature of any specific duties owed by a pharmacy business or owner under the CSA separate and apart from the duties of an individual pharmacist;

- whether and to what extent a pharmacy business or owner is required under the CSA to share a pharmacist's refusal to fill a prescription for a particular doctor with all other pharmacists it employs;

- whether and to what extent a pharmacy business or owner is required under the CSA to collect, aggregate, analyze, and/or retain dispensing data, and, if so, what types of dispensing data;

- whether and to what extent a pharmacy business or owner is required under the CSA to provide particular types of data or data analysis to its pharmacists, and, if so, what types of data or data analysis.

## VI. Conclusion

For the foregoing reasons, DEA should grant the petition for rulemaking and publish either a notice of proposed rulemaking or an advanced notice of public rulemaking concerning the issues identified above.

# Exhibit 2

| | |
|---|---|
| **From:** | Rusconi, Margo |
| **To:** | Shah, Pratik; Tysse, James |
| **Subject:** | FW: Walmart Rulemaking Petition |
| **Date:** | Wednesday, December 2, 2020 2:30:02 PM |

FYI

**Margo Rusconi**

**AKIN GUMP STRAUSS HAUER & FELD LLP**

Direct: +1 202.887.4163 | Internal: 24163

**From:** Prevoznik, Thomas W. <thomas.w.prevoznik@usdoj.gov>
**Sent:** Wednesday, December 2, 2020 2:29 PM
**To:** Rusconi, Margo <mrusconi@akingump.com>
**Cc:** ODLP <ODLP@usdoj.gov>
**Subject:** RE: Walmart Rulemaking Petition

**EXTERNAL Email**

Ms. Rusconi,
DEA acknowledges receipt of your petition on behalf of Walmart. Thanks
tom

**From:** Rusconi, Margo <mrusconi@akingump.com>
**Sent:** Tuesday, November 24, 2020 6:08 PM
**To:** Shea, Timothy J <TJShea@dea.usdoj.gov>; McDermott, William T. (Tim) <WTMcDermott@DEA.USDOJ.GOV>; Prevoznik, Thomas W. <TWPrevoznik@dea.usdoj.gov>; ODLP <ODLP@dea.usdoj.gov>
**Cc:** Shah, Pratik <pshah@akingump.com>
**Subject:** Walmart Rulemaking Petition

Dear Mr. Shea,
Attached please find Walmart Inc.'s petition for agency rulemaking regarding the obligations of prescribing physicians, pharmacists, and pharmacy owners under the Controlled Substances Act. Paper copies of the attached petition will be delivered via UPS.
Sincerely,
Margo Rusconi

**Margo Rusconi**

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# Exhibit 3

Akin Gump
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**PRATIK A. SHAH**
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pshah@akingump.com

May 24, 2021

Tom Prevoznik
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

**Re:** ***Rulemaking Petition To Clarify Obligations Of Opioid Dispensers Under The Controlled Substances Act***

Dear Mr. Prevoznik:

It has been six months since Walmart, Inc. submitted its petition for agency rulemaking regarding the obligations of prescribing physicians, pharmacists, and pharmacy owners under the Controlled Substances Act. Yet the DEA has not responded to the petition (other than your email acknowledgment of receipt on December 2, 2020).

When parties file a petition for agency rulemaking, the Administrative Procedure Act requires the agency to answer within a reasonable time. *See* 5 U.S.C. § 555(b) (requiring an agency to "conclude a matter presented to it" within "a reasonable time"). "If an agency fails to respond to a petition, courts have the authority to 'compel agency action unlawfully withheld or unreasonably delayed.'" *Families for Freedom v. Napolitano*, 628 F. Supp. 2d 535, 540 (S.D.N.Y. 2009) (quoting 5 U.S.C. § 706(1)).

Given the time that has already passed, we ask that the DEA provide its position on the pending rulemaking petition by June 7, 2021. Thank you for your attention to this important matter.

Sincerely,

Pratik A. Shah
*Counsel for Walmart Inc.*